REMARKS

Summary of Facts

In the first Office Action issued March 29, 2000, the Examiner made a Restriction Requirement. Specifically, the Examiner restricted the claims into the following two groups:

Group I, claims 1-8, drawn to a contraceptive process; and

Group II, claims 9-12, drawn to kits.

See page 3 of the March 29, 2000 Office Action. By prior telephonic election, applicants had elected Group I, i.e., a contraceptive process. Thus, the Examiner indicated that kit claims 9-12 were withdrawn from consideration as being drawn to a non-elected invention. It should be noted that original claim 8 was in fact drawn to a kit and, thus, should have initially been included in Group II.

In a Reply filed September 25, 2002, applicants' cancelled claims 1, 2, and 13, leaving claim 14 as the only independent claim drawn to a method of contraception. However, at the same time, applicants added new claims 36-56, all of which were drawn to methods of contraception. Claims 36, 37, 38 and 56 were independent. Method claim 39 was directly dependent (improperly) on combination claim 31. Claims 40-55 were dependent, directly or indirectly, on method claim 38. Thus, as a result of the filing of the September 25, 2002 Reply, claims 3-12, and 14-56 were pending. Of these claims, claims 9-12, drawn to kits were withdrawn from consideration, claim 8 was also drawn to a kit, claims 31-35 were drawn to combinations, and claims 3-7, 14-30 and 36-55 were drawn to the elected invention, i.e., a method of contraception.

In the following Office Action issued December 18, 2002, the Examiner stated that claims 8-12 and 31-56 were withdrawn from consideration. The only reason given by the Examiner for withdrawing these claims was the following:

> New claim 36 and all its dependent claims 38-56 would require a separate search and would have been restricted if originally filed. It would be a burden on the Examiner to search all the inventions as presently claimed. Note, that special technical feature is one that contributes to prior art.

> Claims do not have unity of invention based on the estrogen/gestagen components as claimed being the special technical feature. The alleged special technical feature has not been found to avoid the prior art; it cannot provide support for unity of invention under PCT Rule 13.1-13.2 guidelines.

These comments do not address claims 31-35 and 37 at all. Further, they incorrectly state the dependency of claims 38 and 39. **But, more importantly, they do not address the fact that claims 36-56 are all directed to the elected invention, i.e. they are all drawn to methods of contraception.**

In a Reply filed April 8, 2003, applicants corrected the dependency of claim 39 (so that it depended from method claim 38, rather than combination claim 31) and added new claims 57-69, all of which were drawn to the elected invention of methods of contraception. Claims 57, 62, and 67-69 were dependent on method claim 14 (which was under examination) and claims 58-61 and 63-66 were each dependent on claims 36, 37, 38 or 56. Applicants at the same time argued that claims 36-56 should not have been withdrawn from consideration.

> Independent claims 36, 37, 38, and 56 are all directed to a method of contraception in a female mammal. The same is true for elected independent claim 14. Claims 36, 37, 38, and 56 all recite, during a period of at least 28 days (e.g., 28-84 days), administering a gestagen and during the last 5-10 days of the period administering a gestagen and a natural estrogen. The same is true for elected independent claim 14.
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> Thus, it is a clear that the subject matter of claims 36, 37, 38, 56, and the claims dependent thereon is undeniably related to the subject matter being examined. There is nothing of record to support the allegation that a separate search is required. There is nothing of record to support that there is any serious burden imposed on the Examiner in examining these claims with the elected subject matter.

See page 3 of Reply filed April 8, 2003.

Thereafter, the Examiner issued another Office Action on June 19, 2003 , the Summary of

which stated that claims 8-12 and 31-69 were withdrawn from consideration. The Office Action did not comment further on the Restriction Requirement or applicants' rebuttal thereof, except to state that "Request for consideration of examination of claims 36-56 is denied because the claims are not dependent on claim 14."

On September 22, 2003, applicants filed another Reply in which claims 8-12 and 31-35 were cancelled, and new claims 70-77 were added. **New claims 70-77 were all directed to the elected invention of methods of contraception and were all dependent on claim 14, the independent claim under examination.** Thus, as a result of this Reply, all pending claims were drawn to the elected invention of methods of contraception. Applicants again rebutted the Examiner's action in holding claims 56-69 as withdrawn from consideration.

Thereafter, the Examiner issued a Final Office Action on January 26, 2004. The Summary of the Office Action stated that 36-77 were withdrawn from consideration. The Office Action did not comment further on the Restriction Requirement or applicants' rebuttal thereof, except to again state that "Request for consideration of examination of claims 36-56 is denied because the claims are not dependent on claim 14."

Applicants subsequently filed an Appeal Brief. The Examiner responded to the Appeal Brief by issuing a Quayle Action indicating that claims 3-7 and 14-30 are allowable following an Appeal conference on March 9, 2005. As for claims 36-77, the Examiner stated that the claims "were not on appeal and should be cancelled." Here again, the Examiner did not comment further on the Restriction Requirement or applicants' rebuttal thereof.

Request for Rejoinder

All of the withdrawn claims, i.e., claims 36-77, are directed to methods of contraception. The original Restriction grouped the claims into two groups, i.e., claims drawn to a contraceptive process and claims drawn to a kit. All of the pending withdrawn claims fall within the elected group of a contraceptive process. Thus, the original Restriction provides no basis and no rationale for withdrawing claims 36-77 from consideration.

The only other argument made by the Examiner in support of the Restriction (aside from the unsupported conclusory assertions presented in the Office Action of December 18, 2002) is

the assertion that claims 36-56 do not depend from claim 14. However, this argument is irrelevant as it does not provide a basis for Restriction (as discussed further below) and does not dispute the fact that the withdrawn claims are directed to the elected subject matter of contraceptive processes. Moreover, the assertion makes no reference to claims 57-77, and is clearly not applicable to claims 57, 62, and 67-77, all of which depend, directly or indirectly, from claim 14.

Applicants agree that claims 36-56, 58-61, and 63-66 do not depend from claim 14. However, there is no basis set forth in the statues, rules or even the MPEP that justifies withdrawing claims from consideration simply because they do not depend from an independent claim under examination. Since the Examiner has failed, despite applicants' requests, to cite any authority that supports the withdrawal of these claims from examination based solely on dependency, the Restriction Requirement should be withdrawn

Dependency does not determine whether claims are drawn to the same invention. This rationale is akin to arguing that one can only have one independent claim in an application. If there were two independent claims, then necessarily at least one claim would have a different dependency lineage.

The facts show clearly that the subject matter of claims 36-56, 58-61, and 63-66 are drawn to the same general subject matter as the examined claims. Independent claims 36, 37, 38, and 56 are all directed to methods of contraception in a female mammal. The same is true for examined independent claim 14. Claims 36, 37, 38, and 56 all recite, during a period of at least 28 days (e.g., 28-84 days), administering a gestagen and during the last 5-10 days of that period administering a gestagen and a natural estrogen. The same is true for examined independent claim 14. The Examiner has presented no rationale as to why these claims reciting these similar features are directed to different inventions. For the Examiner's convenience, independent claims 36, 37, 38, and 56, along with examined independent claim 14 are reproduced below:

> 14. A method of contraception in a female mammal, comprising administering to said mammal a gestagen over a period of at least 28 days, wherein said period has a first phase and a second phase,
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> wherein said first phase consists essentially of administering an ovulation-inhibiting amount of a gestagen, and

said second phase comprises administering an ovulation-inhibiting amount of a gestagen and a natural estrogen in an amount effective to achieve regular menstrual-like bleeding,

wherein said second phase is the last 5 to 10 days of said period and said first phase is the remainder of said period.

36. A method of contraception in a female mammal, comprising administering to said mammal a daily steroidal preparation over a period of at least 28 days, wherein

during the last 5-10 days of said period said mammal is daily administered a gestagen in an ovulation-inhibiting dose and a natural estrogen, and

during the rest of said period said mammal is daily administered a steroidal preparation consisting essentially of gestagen in an ovulation-inhibiting dose.

37. A method of contraception in a female mammal, daily comprising administering to said mammal a daily steroidal preparation over a period of at least 28 days, wherein

during the last 5-10 days of said period said mammal is daily administered a gestagen in an ovulation-inhibiting dose and a natural estrogen in an amount which is effective for achieving regular menstrual-like bleeding, and

during the rest of said period said mammal is daily administered a steroidal preparation consisting essentially of gestagen in an ovulation-inhibiting dose.

38. A method of providing contraception in a female mammal comprising administering a daily steroid preparation to said female mammal for a period of 28 - 84 days and said period has a first phase and a second phase, wherein the second phase is the last 5 to 10 days of said period and said first phase is the remainder of said period,

wherein during said first phase a gestagen is daily administered in an ovulation inhibiting amount without an estrogen, and during said second phase a natural estrogen and an ovulation-inhibiting amount of a gestagen and are administered daily.

56. A method of providing contraception in a female mammal comprising administering a daily steroid preparation to said female mammal for a period of 28 - 84 days, said period having a first phase and a second phase, wherein the second phase

is the last 5 to 10 days of said period and said first phase is the remainder of said period,

wherein during said first phase a gestagen is daily administered in an ovulation inhibiting amount and the daily amount of gestagen administered remains the same throughout the period, and during said second phase a natural estrogen and an ovulation-inhibiting amount of a gestagen are administered daily.

The subject matter of claims 36, 37, 38, 56, and the claims dependent thereon is undeniably related to the subject matter being examined. There is nothing of record to support the allegation that a separate search is required. There is nothing of record to support that there is any serious burden imposed on the Examiner in examining these claims with the elected subject matter.

In view of the above remarks, applicants respectfully request that claims 36-77 be examined along with the other pending claims.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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